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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/687,336      | 10/16/2003  | John T. Kilcoyne     | 1065-012US05        | 7853             |

28863 7590 10/12/2006  
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EXAMINER

ROGERS, KRISTIN D

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/687,336 | <b>Applicant(s)</b><br>KILCOYNE ET AL. |  |
|                              | <b>Examiner</b><br>Kristin D. Rogers | <b>Art Unit</b><br>3736                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 50-57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 50-51 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brune (5984875) in view of Steffel et al. (4326535). In regard to claims 50 and 51, Brune shows a system for measuring a physiological parameter in the body of patient 1 comprising an implantable sensor 2 and radiofrequency link/transmitter in the form of an ingestible bolus, which measures a physiological parameter indicative of temperature, wherein the sensor 2 transmits the signal indicative of temperature to a receiving unit 4, and wherein the signal includes an identifier in the form of a identification code for indicating the particular sensor from which the signal was sent (column 3, lines 1-5, column 4 lines 59-65 and column 5 lines 52-58). Although the immediate application for the sensor of Brune is for indicating temperature, the reference teaches other physiological parameters can be monitored including pH (column 5 lines 24-28). Brune lacks teaching a plurality of sensors for indicating a gastroesophageal reflux. Steffel et al. shows a system for measuring physiological parameters indicative of gastroesophageal reflux including a plurality of sensors 16 and 17 which are implantable by insertion through the patient's nasal passage and into the esophagus, comprising a pH monitor and radiotelemetry respectively, for measuring a physiological parameter; and the plurality of sensors 16 and 17 transmit a signal indicative of the physiological parameter, and a receiver 32. In regard to claim 55, Brune shows that that identifier comprises a frequency signal identification code (column 3, lines 1-5, column 4 lines 59-65 and column 5 lines 52-58). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Brune with a plurality of pH sensors indicating gastroesophageal reflux as taught by Steffel et al.

since such modification would provide the advantage of more than one measurement parameter for indicating gastroesophageal reflux in a patient.

5. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brune and Steffel et al. in view of Miyawaki et al. (5697384). Brune shows a system for measuring a physiological parameter of the body including a sensor and a processor, but lacks disclosure of each sensor having a microprocessor for receiving signals from the pH monitor. Steffel et al. shows a system for measuring physiological parameters indicative of gastroesophageal reflux including a plurality of implantable sensors 16 and 17, but lacks disclosure of each sensor containing a microprocessor. Miyawaki et al. teaches a device for measuring a physiological parameter and identification of a patient comprising an implantable bolus or pH monitor 1 or 10 in the embodiments of Figures 1 and 8a, microcomputer housed in the controller within the bolus 1 for receiving a signal from the pH monitor and induces the RF transmitter 41 to send an RF signal indicative of the signal measured by the monitor (Figure 3 column 4 line 65 to column 5 line 23) for processing the signal read by the pH monitor. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Brune and Steffel et al. with the implantable sensor including a microprocessor as taught by Miyawaki et al. for the purpose for providing a signal indicative of pH.

6. Claims 53-54 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brune and Steffel et al. in view of Miyawaki et al., and in further view of Kumar et al. (6416471). Brune and Steffel et al. shows a system for measuring physiological parameters indicative of gastroesophageal reflux including a plurality of

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sensors, but does not disclose neither a microprocessor, separate intervals for sampling and transmitting signal data from the pH monitor receiver, that the patient wears the receiver, or a position sensor. In regard to claim 53, Kumar et al. teaches that the sensor 62 is active during a measurement cycle, first interval being defined as collection of data by sensors 62 and processor 70 conditioning the data and storing the data to memory 80. In regard to claim 54, Kumar et al. teaches that the activation of the second interval, defined by the processor 70 transmitting data stored in memory 80 to be uploaded (transmitted) to over communication link 85 (column 15, line 62 to column 16, line 34). In regard to claim 56, Kumar et al. teaches a system for monitoring and capturing physiological signs of a patient including a receiver 20 configured to be worn by the patient. In regard to claim 57, Kumar teaches a receiver that comprises circuitry via a sensor for sensing the position of the patient (column 11, lines 35-43). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Brune and Steffel et al. with a microprocessor, separate intervals for sampling and transmitting signal data from the pH monitor, a receiver and a position sensor as taught by Kumar et al. since such modification would provide a processor for executing a separate measuring cycle and transmitting of data, a receiver configured to be worn by the patient and a position sensor to sense and record the position of a patient.

***Response to Arguments***

7. Applicant's arguments with respect to claims 50-57 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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*KDR*

KDR

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